

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

74-739

CHEMISTRY REVIEW(S)

OFFICE OF GENERIC DRUGS
DIVISION OF CHEMISTRY II

ANDA REVIEW

1. CHEMIST'S REVIEW NO. 5
2. ANDA # 74-739
3. NAME AND ADDRESS OF APPLICANT
Copley Pharmaceutical Inc.
Attention: I. Nudelman
Canton Commerce Center
25 John Road
Canton, MA 02021
4. LEGAL BASIS for ANDA SUBMISSION
Innovator Drug: Cordarone/Wyeth Ayerst NDA# 18972 approved 12.24.85
Patent Certification: page 12-none remaining; Exclusivity: page 13-
none indicated in orange book
5. SUPPLEMENT(s) None
6. PROPRIETARY NAME None
7. NONPROPRIETARY NAME
Amiodarone Hydrochloride Tablets
8. SUPPLEMENT(s) PROVIDE(s) FOR: None
9. AMENDMENTS AND OTHER DATES:

Firm:

08.31.95 - Original
12.03.96 - Amendment
08.22.97 - Amendment
04.07.98 - Amendment
10.13.98 - Amendment

FDA:

05.14.96 - NA letter #1
06.12.97 - NA letter #2
03.06.98 - NA letter #3
09.29.98 - NA letter #4
10. PHARMACOLOGICAL CATEGORY
anti-arrhythmic
11. Rx or OTC
Rx

1. RELATED IND/NDA/DMF(s)

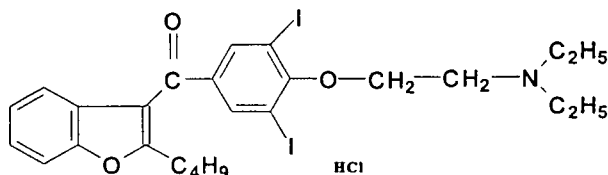
NDA 18972; see element #37 for list of DMFs

13. DOSAGE FORM

Tablet

14. POTENCY

200 mg

15. CHEMICAL NAME AND STRUCTURE

Amiodarone Hydrochloride

 $C_{25}H_{29}I_2NO_3 \cdot HCl$

617.27

CAS#[1977-82-4]

2-Butyl-3-benzofuranyl
4-[2-(diethylamino)ethoxyl
]-3,5-diiodophenyl]
ketone, hydrochloride

16. RECORDS AND REPORTS

See report from Philadelphia District Office, dated 8/11/98 regarding comments concerning the revised methods validation.

17. COMMENTS

This application has been reviewed in accordance with OGD Policy and Procedure Guide #29-90 which states that the review material previously reviewed by another reviewer should not be re-reviewed.

18. CONCLUSIONS AND RECOMMENDATIONS

All deficiencies have been resolved satisfactorily.

19. REVIEWER:

Karen A. Bernard, Ph.D.

DATE COMPLETED:

11/2/98

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Contain Trade Secret,
Commercial/Confidential
Information and are not
releasable.

11/2/98

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